



BILLING CODE: 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

**Government-Owned Inventions; Availability for Licensing**

AGENCY: National Institutes of Health

ACTION: Notice

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing and/or co-development in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing and/or co-development.

ADDRESSES: Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD, 20850-9702.

FOR FURTHER INFORMATION CONTACT: Information on licensing and co-development research collaborations, and copies of the U.S. patent applications listed below may be obtained by contacting: Attn. Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD, 20850-9702, Tel. 240-276-5515 or email [ncitechtransfer@mail.nih.gov](mailto:ncitechtransfer@mail.nih.gov). A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Title of invention:

Vaccines for HIV

Description of Technology:

Although the development of an effective HIV vaccine has been an ongoing area of research, the high variability in HIV-1 virus strains has represented a major challenge in successful development. Ideally, an effective candidate vaccine would provide protection against the majority of clades of HIV. Two major challenges are immunodominance and sequence diversity. One strategy for overcoming these two issues is to identify the conserved regions of the virus and exploit them for use in a targeted therapy.

Researchers at the National Cancer Institute's Vaccine Branch used conserved elements (CEs) of the polypeptides Gag and Env as immunogenic compositions to induce an immune response to HIV-1 envelope polypeptides and Gag polypeptides. conserved elements (CEs) of the polypeptides Gag and Env as immunogenic compositions to induce an immune response to HIV-1 envelope polypeptides and Gag polypeptides. This invention is based, in part, on the discovery that administration of one or more polypeptides comprising CEs, separated by linkers and collinearly arranged, of HIV Env or Gag CE proteins can provide a robust immune response compared to administration of a full-length Env or Gag protein. The Env-CE DNA vaccines were tested in a rhesus macaque model and were able to induce a cellular and humoral immune response in this model whereas vaccination with the full length DNA did not produce the same effect.

A robust increase in immunity was observed when rhesus macaques were subjected to a prime-boost protocol. First, rhesus macaques were primed with Env-CE DNA and boosted with full length Env resulting in an observed increase in both the cellular and humoral responses. A further increase in immune response was observed from priming with CE and boosting with a combination of CE and full length DNA resulting in a significantly improved breadth of immune responses. These improved protocols may help solve the immunodominance problem observed in current protocols. This is considered a major obstacle for HIV vaccine development. The CE vaccines described by this invention have potential for use as prophylactic and therapeutic HIV vaccines.

#### Potential Commercial Applications:

- HIV vaccines

#### Value Proposition:

- Addresses two key hurdles faced by current HIV vaccines: sequence diversity of HIV and immunodominance.
- Induces cross-clade specific immune response.
- The prime-boost immunization regimen is not limited to HIV, but can be employed to improve the induction of immune responses to any subdominant epitopes (cellular or humoral) to increase breadth, magnitude and quality of the immune response.

Development Stage:

Pre-clinical (in vivo validation)

Inventor(s):

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Intellectual Property:

HHS Reference #E-087-2015/0-US-01, corresponding to US Provisional Patent App. # 62/161,123, filed on May 13, 2015, entitled: HIV Env Conserved Element DNA Vaccine.

HHS Reference #E-009-2016/0-US-01, corresponding to US Provisional Patent App.#62/241,599, filed on October 14, 2015, entitled: Prime-Boost combination vaccine to Expand Breadth of Immunological Response.

HHS Reference #E-087-2015/0-PCT-02; corresponding to International Patent App.# PCT/US2016/032317; filed on May 13, 2016, entitled: Methods and Compositions for inducing an immune response using Conserved Element Constructs.

Publications:

- Kulkarni, V. *et al. PLoS One*;9:e86254. 2014.  
<http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0086254>
- Kulkarni, V. *et al. PLoS One* Oct 22;9(10):e111085. doi:  
10.1371/journal.pone.0111085. eCollection, 2014.  
<http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0111085>

Related Technologies: HHS Reference #E-132-2012/0 Method of Altering the Immunodominance Hierarchy of HIV Gag by DNA Vaccine Expressing Conserved Regions.

Contact Information:

Requests for copies of the patent application or inquiries about licensing, research collaborations, and co-development opportunities should be sent to John D. Hewes, Ph.D., email: [john.hewes@nih.gov](mailto:john.hewes@nih.gov).

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